

Anexa 118 Specificație tehnică completată

Model: MAC 2000, Producător: GE Medical Systems, GE Healthcare, Tara: USA/SUA

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificarea tehnică deplină completată de către autoritatea ofertantă
Electrocardiograf cu 12 canale, caracteristici avansate Cod 260231 Descriere Electrocardiograf cu 12 canale, care înregistrează, printează și/sau interpretează ECG de la o singură sau mai multe derivații simultan, cu display color. Parametrul Specificația Tip pacient adult, pediatric Numărul de canale de procesare 12 Configurația Portabil da Derivațiile Tip înregistrare auto și manual Sensivitatea 2.5, 5, 10, 20, 40 mm/mv Semnal de calibrare 1 mV, $\pm 2\%$ Gama de frecvență De diagnostic 0.05-150 Hz Filtru muscular 25, 35Hz Filtru frecvență joasă 0.05, 0.16, 0.25, 0.32, 0.5, 0.67Hz Filtru frecvență înaltă 20, 40, 100, 150Hz Filtru de rețea 50 Hz Impedanța de intrare ≥ 50 M Ohm Gama de rejecție a modului comun la 50 Hz > 110 dB Convertor analog-digital ≥ 24 bit Scurgeri spre pacient prin electrozi ≤ 10 μA Detector de pacemaker da Indicator deconectare electrod acustic sau vizual da Imprimantă Termică încorporată Mărimea hîrtiei ≥ 210 mm da Să se indice numele derivației printate da Viteza de înscriere 5, 10, 25, 50 mm/s Densitatea imprimării 8 dpi/mm (rezoluție verticală) și 40 dpi/mm (rezoluție orizontală) la viteza de 25 mm/s Acuratețea $\pm 5\%$ (axa x), $\pm 5\%$ (axa y) Derivațiile înscrise minim 12 Numărul de derivații înscrise simultan 3, 6, 12 Hîrtia termică să fie compatibilă și de la alți producători de hîrtie cu dispozitivul ECG da Display Grafic, LCD TFT color da Monitorizarea pe display: data, ora, sensibilitatea, viteza de înscriere, filtru, derivațiile da	Electrocardiograf cu 12 canale, caracteristici avansate DA Cod 260231 Descriere Electrocardiograf cu 12 canale, care înregistrează, printează și/sau interpretează ECG de la o singură sau mai multe derivații simultan, cu display color DA Parametrul Specificația Tip pacient adult, pediatric DA Numărul de canale de procesare 12 DA Configurația Portabil DA Derivațiile Tip înregistrare auto și manual DA Sensivitatea 2.5, 5, 10, 20, 40 mm/mV DA Semnal de calibrare 1 mV, $\pm 2\%$ DA Gama de frecvență De diagnostic 0.04-150 Hz DA Filtru muscular 25, 35Hz DA Filtru frecvență joasă 0.04, 0,56 Hz DA Filtru frecvență înaltă 20, 40, 100, 150 Hz DA Filtru de rețea 50 Hz si de 60 Hz DA Impedanța de intrare ≥ 10 M Ohm la 10 Hz Gama de rejecție a modului comun la 50 Hz > 135 dB DA Convertor analog-digital ≥ 24 bit DA Scurgeri spre pacient prin electrozi ≤ 10 μA DA Detector de pacemaker DA Indicator deconectare electrod acustic sau vizual DA Imprimantă Termică încorporată DA Mărimea hîrtiei – 295 mm DA Să se indice numele derivației printate DA Viteza de înscriere 5, 12,5, 25, 50 mm/s DA Densitatea imprimării 8 dpi/mm (rezoluție verticală) și 40 dpi/mm (rezoluție orizontală) la viteza de 25 mm/s DA Acuratețea $\pm 5\%$ (axa x), $\pm 5\%$ (axa y) DA Derivațiile înscrise - 12 DA Numărul de derivații înscrise simultan 3, 6, 12 DA Hîrtia termică să fie compatibilă și de la alți producători de hîrtie cu dispozitivul ECG DA Display Grafic, LCD TFT color DA Monitorizarea pe display: data, ora, sensibilitatea, viteza de înscriere, filtru, derivațiile DA

Marime ecran ≥ 7 inch Rezoluția $\geq 800 \times 480$ pix Touchscreen da Numărul de derivații afișate simultan 12 Posibilitatea transmiterii datelor la un sistem de management al datelor ECG Ethernet / USB / SD card da Format date ECG BMP / JPG / GIF / PDF / XML / DICOM da Memorie ≥ 200 înregistrări ECG da Soft specializat pentru analiza rezultatelor ECG la calculator da Posibilitatea introducerii rapide a datelor pacientului Nume, ID, vîrsta, sex, greutate, înălțimea Ajustarea automată a izoliniei da Identificarea aritmiei da Ritmului cardiac Diapazon 30 - 300 BPM Acuratețea ± 1 BPM Interpretarea Sistem de interpretare a datelor ECG da Măsurări PR, QT, QTC, P, QRS, T, HR; Timpul interpretării minim 10 s Alimentarea 220 V, 50 Hz Baterie internă reîncărcabilă da Timp operare autonomă ≥ 2 h Protecție defibrilator ≥ 400 J Indicatori vizuali contact slab sau lipsă de contact da status sistem da deconectare alimentare rețea da baterie descărcată da Accesorii Cablul pacient cu set de electrozi pectorali de tip pară (6 buc.) și membranari de tip clește (4 buc.) 2 set. Hîrtie termică 30 buc. Gel de contact 1 litru Troleu pe roțile indicați modelul oferit model troleu pe roțile da ≥ 4 roți da ≥ 2 roți cu frînă da mîner pentru transportarea standului da coș pentru accesorii da braț articulat pentru electrozi ECG da suport pentru gel de contact da ajustarea pe înălțime optional sistem de fixare dispozitivului de suport da	Marime ecran - 7 inch DA Rezoluția - 800x480 pix DA Touchscreen NU Numărul de derivații afișate simultan 12 DA Posibilitatea transmiterii datelor la un sistem de management al datelor ECG Ethernet / USB / SD card DA Format date ECG BMP / JPG / GIF / PDF / XML / DICOM DA Memorie - 200 înregistrări ECG DA Soft specializat pentru analiza rezultatelor ECG la calculator DA optional Posibilitatea introducerii rapide a datelor pacientului Nume, ID, vîrsta, sex, greutate, înălțimea DA Ajustarea automată a izoliniei DA Identificarea aritmiei DA Ritmului cardiac Diapazon 30 - 300 BPM DA Acuratețea ± 1 BPM DA Interpretarea Sistem de interpretare a datelor ECG DA Măsurări PR, QT, QTC, P, QRS, T, HR; DA Timpul interpretării minim 10 s DA Alimentarea 220 V, 50 Hz DA Baterie internă reîncărcabilă da Timp operare autonomă - 6 h de monitoring continuu fara printare. Protecție defibrilator - 400 J DA Indicatori vizuali contact slab sau lipsă de contact DA status sistem DA deconectare alimentare rețea DA baterie descărcată DA Accesorii Cablul pacient cu set de electrozi pectorali de tip pară (6 buc.) și membranari de tip clește (4 buc.) 2 set. DA Hîrtie termică 30 buc. DA Gel de contact 1 litru DA Troleu pe roțile este produs de producator ca denumire de baza ECG Card MAC 5500/2000 DA ≥ 4 roți DA ≥ 2 roți cu frînă DA mîner pentru transportarea standului DA coș pentru accesorii DA braț articulat pentru electrozi ECG DA suport pentru gel de contact DA ajustarea pe înălțime optional sistem de fixare dispozitivului de suport DA
--	---



EC DECLARATION OF CONFORMITY

TF – DOC1430163 (CE-M-201)

Following the provisions of the medical devices directive 93/42/EEC, ROHS directive 2011/65/EU and Radio Equipment Directive 2014/53/EU

EG-KONFORMITÄTSERKLÄRUNG

Entsprechend der Anforderung der Medizin Produkte Richtlinie 93/42/EEC, der Richtlinie 2011/65/EU und radio - richtlinie richtlinie 2014/53/EU

We/ Wir

Manufacturer
Hersteller

**GE Medical Systems
Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223, USA**

EU Authorized Representative
Autorisierter EU-Vertreter

**GE Medical Systems
Information Technologies GmbH
Munzingerstrasse 5
79111 Freiburg, Germany**

Manufacturing site (if different from manufacturer)
Fertigungsstätte (falls anders als Hersteller)

**Wipro GE Healthcare Private Limited
No. 4, Kadugodi Industrial Area
Bangalore 560067, Karnataka, India**

**GE Healthcare Finland OY
Kuortaneenkatu 2
Helsinki, FIN-00510, Finland**

**Critikon de Mexico S. de R.L. de C.V.
Calle valle del cedro 1551 Juarez Mexico 32575**

Declare under our sole responsibility that the class **Ila** medical device:
*Erklären unter alleiniger Verantwortung, dass das Medizinprodukt der Klasse **Ila**:*

MAC 2000 ECG Analysis System

Ref. : see addendum/ *oder siehe Anhang*

GMDN Code: 16231

UMDNS Code: 11411

Classification rule (93/42/EC Annex IX) / *Klassifizierungsregel (93/42/EG Anhang IX)*: **Rule 10**

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161



To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Auf das sich diese Erklärung bezieht, den Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte, die für das Produkt gelten, und den Anforderungen der Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten entspricht.

This medical device conformity is based on the following elements:

Diese Medizinprodukte Konformität basiert auf den folgenden Elementen:

- Information included in the documents:
Technical Documentation/DHF Ref./ réf: **DOC0851945**, of the product to which this declaration relates.
Informationen, die in den Dokumenten enthalten sind:
Technische Dokumentation/DHF-Ref./réf: **DOC0851945** des Produkts, auf das sich diese Erklärung bezieht.

- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by LNE/G-MED France, (NB #0459) / Certificate No. 7550.

The medical device bears the mark



- *EG-Zertifikat: Genehmigung des kompletten Qualitätssicherungssystems (Anhang II der Richtlinie 93/42/EWG über Medizinprodukte), ausgestellt von G-MED France, NB #0459 / Zertifikat Nr. 7550.*
- List of harmonized standards applied for CE marking as in Appendix 1
Liste der harmonisierten Normen, die für die CE-Kennzeichnung angewendet wurden in anhang 1.

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161



We, manufacturer, declare under our sole responsibility that:

Wir, Hersteller, Erklären unter unserer alleinigen Verantwortung

MAC 2000 embedded with MSD45N WLAN module

To which this declaration relates is in conformity with the requirements of the Radio Equipment Directive 2014/53/EU which applies to it.

die erklärung bezieht, in übereinstimmung mit den anforderungen der funkgeräte richtlinie 2014/53/EU

This conformity is based on the following elements:

Diese Konformität basiert auf den folgenden Elementen:

- The device conforms to the Directive 2014/53/EU through Annex II-Internal Production Control.
das gerät mit der richtlinie 2014 / 53 / eu über anhang ii- interne fertigungskontrolle
- List of standards applied for CE marking as in Appendix 2.
Liste der Normen, die für die CE-Kennzeichnung angewendet wurden in anhang 2.

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Appendix 1/ *Anhang 1*

Relevant Standards/ <i>relevante normen</i>
EN 60601-1:2006/A1:2013 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2:2015 Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-2-25:2015 Medical Electrical Equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
EN 60601-1-6:2010+A1:2015 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes
EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013 Information supplied by the manufacturer with medical devices

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161



Appendix 2/ Anhang 2

Relevant Standards/ relevante normen
EN 300 328 V2.2.2 Wideband transmission systems; Data transmission equipment operating in the 2.4GHz ISM band and using wideband modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 893 V2.1.1 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V2.2.3 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17 V3.2.2 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 62311:2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
EN 60601-1-2:2007 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
EN 60601-1:2006/A1:2013 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance

This EC declaration of conformity supersedes the previous declaration dated 28 October 2020

Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 28 October 2020

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161



ADDENDUM TO THE EC DECLARATION OF CONFORMITY
ERGÄNZUNG ZUR KONFORMITÄTSERKLÄRUNG

Product Description <i>Produktbezeichnung</i>	Catalog Designation <i>Katalogbezeichnung</i>
MAC 2000	2063587-001
<u>Unit Options</u>	
MAC 2000 UNIT	2063587-017
MAC 2000 KISS UNIT	2063587-018
MAC 2000 ECG Pharma	2063587-171
MAC 2000 UNIT with embedded wifi	2063587-223
<u>MAC 2000 STRESS OPTION</u>	
MAC 2000 STRESS	2063587-140
<u>STARTER KIT SELECTION</u>	
MAC 2000 STARTER KIT AHA VALUE REUSABLE	2063587-500
MAC 2000 STARTERKIT AHA MULTILINK WITH ECG CLIP	2063587-501
MAC 2000 STARTER KIT AHA MULTILINK WITH ADAPTER	2063587-503
MAC 2000 STARTER KIT IEC VALUE REUSABLE	2063587-504
MAC 2000 STARTER KIT IEC MULTILINK REUSABLE	2063587-505
MAC 2000 STARTER KIT IEC MULTILINK WITH ECG CLIP	2063587-506
MAC 2000 STARTER KIT IEC MULTILINK WITH ADAPTER	2063587-508
MAC 2000 STARTER KIT IEC MULTILINK REUSABLE	2063587-509
MAC 2000 STARTER KIT AHA VALUE WITH CLIP	2063587-510
MAC 2000 STARTER KIT IEC VALUE WITH CLIP	2063587-511
<u>Language Options</u>	
MAC 2000 ENG LANGUAGE NON-STRESS	2063587-019
MAC 2000 GER LANGUAGE NON-STRESS	2063587-020
MAC 2000 FRE LANGUAGE NON-STRESS	2063587-021
MAC 2000 SPA LANGUAGE NON-STRESS	2063587-022
MAC 2000 ITA LANGUAGE NON-STRESS	2063587-023
MAC 2000 JAP LANGUAGE NON-STRESS	2063587-024
MAC 2000 SWE LANGUAGE NON-STRESS	2063587-025
MAC 2000 DUT LANGUAGE NON-STRESS	2063587-026
MAC 2000 HUN LANGUAGE NON-STRESS	2063587-027
MAC 2000 RUS LANGUAGE NON-STRESS	2063587-028
MAC 2000 FIN LANGUAGE NON-STRESS	2063587-029
MAC 2000 CHI LANGUAGE NON-STRESS	2063587-030
MAC 2000 CZECH LANGUAGE NON-STRESS	2063587-031

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161



Product Description Produktbezeichnung	Catalog Designation Katalogbezeichnung
<u>Language Options (Continued)</u>	
MAC 2000 POL LANGUAGE NON-STRESS	2063587-032
MAC 2000 NOR LANGUAGE NON-STRESS	2063587-033
MAC 2000 SLO LANGUAGE NON-STRESS	2063587-034
MAC 2000 BRA POR LANGUAGE NON-STRESS	2063587-035
MAC 2000 DAN LANGUAGE NON-STRESS	2063587-036
MAC 2000 KOR LANGUAGE NON-STRESS	2063587-037
MAC 2000 EURO POR LANGUAGE NON-STRESS	2063587-038
MAC 2000 CRO LANGUAGE NON-STRESS	2063587-039
MAC 2000 GRE LANGUAGE NON-STRESS	2063587-040
MAC 2000 TUR LANGUAGE NON-STRESS	2063587-041
MAC 2000 EST LANGUAGE NON-STRESS	2063587-042
MAC 2000 LIT LANGUAGE NON-STRESS	2063587-043
MAC 2000 ROM LANGUAGE NON-STRESS	2063587-044
MAC 2000 BUL LANGUAGE NON-STRESS	2063587-045
MAC 2000 SER LANGUAGE NON-STRESS	2063587-046
MAC 2000 EGYPT LANGUAGE NON-STRESS	2063587-141
MAC 2000 VENEZUELA-SPA LANGUAGE NON-STRESS	2063587-142
MAC 2000 MEXICO-SPA LANGUAGE NON-STRESS	2063587-143
MAC 2000 INDONESIA LANGUAGE NON-STRESS	2063587-144
MAC 2000 ARG-SPA LANGUAGE NON-STRESS	2063587-166
MAC 2000 VIT LANGUAGE NON-STRESS	2063587-177
MAC 2000 LATVIAN LANGUAGE NON-STRESS	2063587-179
MAC 2000 KAZAKH LANGUAGE NON-STRESS	2063587-182
MAC 2000 TAIWAN LANGUAGE NON-STRESS	2063587-184
MAC 2000 MALAYSIA LANGUAGE NON-STRESS	2063587-190
MAC 2000 Pharma Japan	2063587-172
MAC 2000 ENG LANGUAGE W/STRESS	2063587-047
MAC 2000 GER LANGUAGE W/STRESS	2063587-048
MAC 2000 FRE LANGUAGE W/STRESS	2063587-049
MAC 2000 SPA LANGUAGE W/STRESS	2063587-050
MAC 2000 ITA LANGUAGE W/STRESS	2063587-051
MAC 2000 JAP LANGUAGE W/STRESS	2063587-052
MAC 2000 SWE LANGUAGE W/STRESS	2063587-053
MAC 2000 DUT LANGUAGE W/STRESS	2063587-054
MAC 2000 HUN LANGUAGE W/STRESS	2063587-055
MAC 2000 RUS LANGUAGE W/STRESS	2063587-056
MAC 2000 FIN LANGUAGE W/STRESS	2063587-057
MAC 2000 CHI LANGUAGE W/STRESS	2063587-058
MAC 2000 CZECH LANGUAGE W/STRESS	2063587-059
MAC 2000 POL LANGUAGE W/STRESS	2063587-060

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161



Product Description Produktbezeichnung	Catalog Designation Katalogbezeichnung
<u>Language Options (Continued)</u>	
MAC 2000 NOR LANGUAGE W/STRESS	2063587-061
MAC 2000 SLO LANGUAGE W/STRESS	2063587-062
MAC 2000 BRA POR LANGUAGE W/STRESS	2063587-063
MAC 2000 DAN LANGUAGE W/STRESS	2063587-064
MAC 2000 KOR LANGUAGE W/STRESS	2063587-065
MAC 2000 EURO POR LANGUAGE W/STRESS	2063587-066
MAC 2000 CRO LANGUAGE W/STRESS	2063587-067
MAC 2000 GRE LANGUAGE W/STRESS	2063587-068
MAC 2000 TUR LANGUAGE W/STRESS	2063587-069
MAC 2000 EST LANGUAGE W/STRESS	2063587-070
MAC 2000 LIT LANGUAGE W/STRESS	2063587-071
MAC 2000 ROM LANGUAGE W/STRESS	2063587-072
MAC 2000 BUL LANGUAGE W/STRESS	2063587-073
MAC 2000 SER LANGUAGE W/STRESS	2063587-074
MAC 2000 EGYPT LANGUAGE W/STRESS	2063587-145
MAC 2000 VENEZUELA-SPA LANGUAGE W/STRESS	2063587-146
MAC 2000 MEXICO-SPA LANGUAGE W/STRESS	2063587-147
MAC 2000 INDONESIA LANGUAGE W/STRESS	2063587-148
MAC 2000 ARG-SPA LANGUAGE W/STRESS	2063587-167
MAC 2000 VIT LANGUAGE W/STRESS	2063587-176
MAC 2000 LATVIAN LANGUAGE W/STRESS	2063587-178
MAC 2000 KAZAKH LANGUAGE W/STRESS	2063587-181
MAC 2000 TAIWAN LANGUAGE W/STRESS	2063587-183
MAC 2000 MALAYSIA LANGUAGE W/STRESS	2063587-191
<u>Power Cord Selection</u>	
MAC 2000 N AMERICAN POWERCORD	2063587-085
MAC 2000 EURO POWERCORD	2063587-086
MAC 2000 BRITISH POWER CORD	2063587-087
MAC 2000 ITALIAN POWER CORD	2063587-088
MAC 2000 AUSTRALIAN POWER CORD	2063587-089
MAC 2000 ISRAELI POWER CORD	2063587-090
MAC 2000 SWISS POWER CORD	2063587-091
MAC 2000 INDIAN POWER CORD	2063587-092
MAC 2000 CHINESE POWER CORD	2063587-093
MAC 2000 JAPANESE POWER CORD	2063587-094
MAC 2000 BRAZIL POWER CORD	2063587-095

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161



Product Description Produktbezeichnung	Catalog Designation Katalogbezeichnung
<u>Analysis Options</u>	
MAC 2000 MEASUREMENT BY 12SL	2063587-096
MAC 2000 MEASUREMENT INTERPRETATION BY 12SL	2063587-097
MAC 2000 MEASUREMENT IINTERPRETATION ACITIPI BY 12SL	2063587-098
MAC 2000 MEASUREMENT BY HEART	2063587-099
MAC 2000 MEASUREMENT INTERP BY HEART	2063587-100
<u>Storage And Export Options</u>	
MAC 2000 INT STOR 100 – SDCD PDF/XML/HT	2063587-101
MAC 2000 INT STOR 200 – SDCD PDF/XML/HT	2063587-102
MAC 2000 INT STOR 100 – SDCD XML/HT	2063587-103
MAC 2000 INT STOR 200 – SDCD XML/HT	2063587-104
<u>Workflow Executive Packages Options</u>	
MAC2000 ADT – MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-150
MAC2000 ADT SIMP ORDRS – MUSE LAN SERL CONN – INT STOR 200 -SDCD PDF/XML/HT	2063587-151
MAC2000 ADT ADV ORDRS – MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-152
MAC2000 CARDIOSOFT LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-153
MAC2000 PC LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-154
MAC2000 MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-155
MAC2000 ADT – NON-MUSE LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-157
MAC2000 ADT SIMP ORDRS – NON-MUSE LAN CONN – INT STOR 200-SDCD PDF/XML/HT	2063587-158
MAC2000 ADT ADV ORDRS – NON-MUSE LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-159
MAC2000 SIMP ORDRS - MUSE LAN SERL CONN - INT STOR 200-SDCD /XML/HT	2063587-160
MAC2000 SIMP ORDRS - MUSE LAN SERL CONN - INT STOR 100-SDCD /XML/HT	2063587-161
MAC2000 CARDIOSOFT LAN SERL CONN - INT STOR 200 - SDCD XML/HT	2063587-162
MAC2000 CARDIOSOFT LAN SERL CONN - INT STOR 100- SDCD XML/HT	2063587-163
MAC2000 MUSE LAN SERL CONN - INT STOR 200 - SDCD XML/HT	2063587-164
MAC2000 MUSE LAN SERL CONN - INT STOR 100- SDCD XML/HT	2063587-165
Pharma Workflow Option Pack	2063587-222
Pharma Workflow Option Pack 1 - Japan	2063587-221
<u>WIFI CHNL 11 /Modem Option</u>	
MAC 2000 WIFI BRIDGE CHANNEL 11	2063587-169

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161



Product Description Produktbezeichnung	Catalog Designation Katalogbezeichnung
<u>WIFI CHNL 13 /Modem Option</u>	
MAC 2000 MODEM	2063587-112
MAC 2000 WIFI BRIDGE CHANNEL 13	2063587-170
<u>Pharma Options</u>	
MAC 2000 AUDIT TRAIL EXPORT	2063587-122
MAC 2000 CT DATA GUARD	2063587-123
MAC 2000 PHARMA PKG	2063587-168
<u>Barcode Options</u>	
MAC 2000 ENG BARCODE	2063587-124
MAC 2000 GER BARCODE	2063587-125
MAC 2000 FRE BARCODE	2063587-126
MAC 2000 SPA BARCODE	2063587-127
MAC 2000 ITA BARCODE	2063587-128
MAC 2000 SWE BARCODE	2063587-129
MAC 2000 DUT BARCODE	2063587-130
MAC 2000 HUN BARCODE	2063587-131
MAC 2000 RUS BARCODE	2063587-132
MAC 2000 FIN BARCODE	2063587-133
MAC 2000 CZE BARCODE	2063587-134
MAC 2000 NOR BARCODE	2063587-135
MAC 2000 SLO BARCODE	2063587-136
MAC 2000 POR BARCODE	2063587-137
MAC 2000 DAN BARCODE	2063587-138
MAC 2000 BARCODE SW only	2063587-185
<u>RR OPTION</u>	
MAC 2000 RR ANALYSIS	2063587-106
<u>FULL DISCLOSURE OPTION Optional</u>	
MAC 2000 FULL DISCLOSURE	2063587-201
<u>EMBEDDED WIRELESS OC</u>	
MAC2000 EMBEDDED WIRELESS	2063587-174
MAC 2000 SW OPTION for EMBEDDED WIRELESS	2063587-224

March 15, 2021

Lee, Bush

Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 60146867 0001

Organization: GE Medical Systems
Information Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226
USA

Scope: Design, Development, and Manufacture of Patient Monitoring Systems,
Cardiology ECG Recording and Analysis Systems, Invasive Cardiology
Equipment Systems and Medical Software

TÜVRheinland

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 32090997.003

Effective date: 2020-08-12

Expiry date: 2023-03-11

Issue date: 2020-08-12



Bal Balazs

Balazs Bozsik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60131555 0001

Report No.: 21198147 012

Manufacturer: getemed Medizin- und
Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

Products: Vital signs monitors, cardiac function diagnostic
and telemonitoring systems
(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60088821 0001

Expiry Date: 2023-10-03

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-10-04

Date: 2018-08-02

Notified Body



Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC
concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to

Certificate

Registration No.: HD 60131555 0001

Report No.: 21198147 012

Manufacturer: getemed Medizin- und
Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

Products included:

Recorder, Long-term ECG portable
- CardioMem[®] and SEER

Long-term ECG evaluation system
- CardioDay[®]

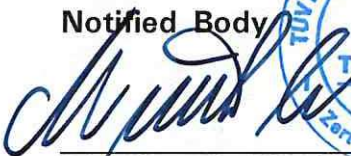
Electrocardiograph, multi channel
- CardioLink[®]

Pulse oximeter, physiological monitoring system, neonatal
- VitaGuard[®] with VitaWin[®]

ECG-monitor, telemetric
- PhysioMem[®]

Date: 2018-08-02

Notified Body



Dipl.-Ing. I. Munkler

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60131555 0001
Report No.: 21198147 012

Manufacturer: getemed Medizin- und
Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

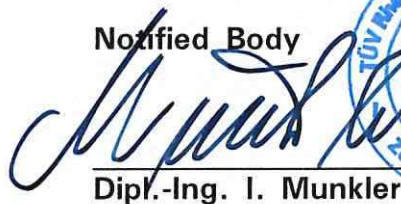
Sites included:

getemed Medizin- und Informationstechnik AG
Oderstr. 77, 14513 Teltow, Germany

getemed Medizin- und Informationstechnik AG
Otto-Schmerbach-Straße 19, 09117 Chemnitz, Germany

Date: 2018-08-02

Notified Body



Dipl.-Ing. I. Munkler



SIMPLE IS SMART

MAC 2000 ECG Analysis System
Streamlined for your healthcare facility



art

Simple is produ

and simple solutions. Equipment
ogy that delivers clear,
tools that are simple to use.
question. **Simple.**



Easy capture of 10-second ECGs
with one-touch operation



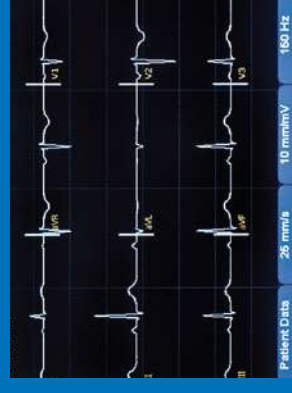
On-screen preview of 12-lead
waveforms and ECG results helps
streamline review and diagnosis



Multiple connectivity and export
options for easy data access,
transfer and storage



**Marquette 12SL ECG analysis
program** with reason statement
for clinical decision support



Connected

Integrate with your existing
systems, so it's easier
to collect and transmit ECG data.
No matter where you need

Supports paperless workflow
with options for bi-directional
communication, including Orders
and ADT query features

Seamless connectivity with your
Electronic Medical Record via EMR
Gateway Pro

Seamless connectivity to **RIS/PACS**
systems using DICOM Gateway

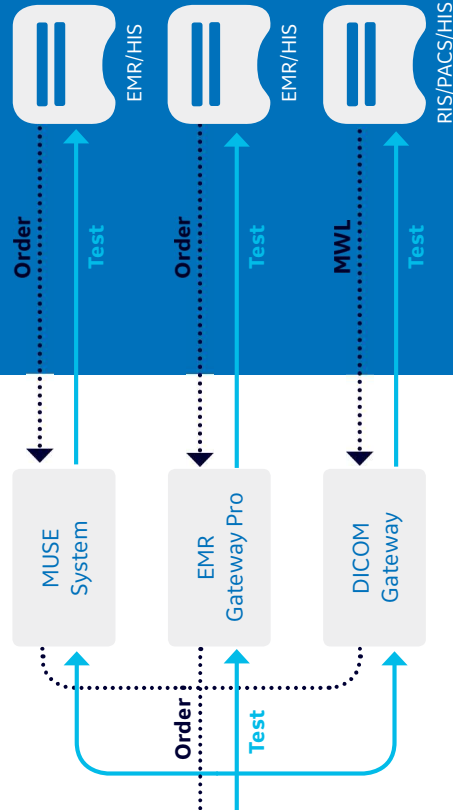
Seamless connectivity with **the MUSE™**
cardiology information system or the
CardioSoft™ program - or send reports
to a shared directory on a PC

Send report to remote locations
using FTPS

Connectivity with LAN, Wi-Fi, serial
port, modem, or SD card

PDF and XML export capabilities

Internal storage for up to 200 ECGs



Simple is reliable

- > **Marquette 12SL ECG analysis program** with measurement and interpretation
- > **Arrhythmia detection** helps maximize rhythm capabilities and minimize paper consumption
- > **ACI-TIPI algorithm** for acute cardiac ischemia
- > **Gender-specific interpretation** provides improved sensitivity to Acute Myocardial Infarction in women
- > **RR analysis** for detection of patterns in heart rate variability^{*}
- > **Full disclosure** to store up to 5 minutes of a single lead in PDF format^{*}

The MAC 2000 delivers the diagnostic insights physicians need. Empowered with the Marquette 12SL analysis program, the system provides a complete set of analysis tools you can trust, because they've been rigorously validated against clinically correlated databases with multiple patient populations. It's clinical decision support made simple.

^{*}RR analysis and full-disclosure are not available in all regions. Please contact your local GE Healthcare representative for more information.

ported



**makes it simple the moment
. Easy installation won't
digital operations.**

ive interface with full keyboard
and ECG Professional won't
ng — more like minutes.

training needs can change with
nvenient computer-based training
earning.

service and support are always just
ur extensive network of trained
are ready so you don't have to
ner way the MAC 2000 embraces
a hassle-free experience.





GE Healthcare provides transformational medical technologies and services to meet the demand for increased access, enhanced quality and more affordable healthcare around the world. GE (NYSE: GE) works on things that matter – great people and technologies taking on tough challenges.

From medical imaging, software & IT, patient monitoring and diagnostics to drug discovery, biopharmaceutical manufacturing technologies and performance improvement solutions, GE Healthcare helps medical professionals deliver great healthcare to their patients.

Imagination at work

©2018 General Electric Company – All rights reserved.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE representative for the most current information.

GE, GE Monogram, CardioSoft, HookUp Advisor, MAC, Marquette, and MIUSE are trademarks of General Electric Company.

All other product names and logos are trademarks or registered trademarks of their respective companies.

GE Healthcare, a division of General Electric Company



MAC[™] 2000

Specification Sheet



Instrument type

Microprocessor augmented automatic electrocardiograph; 10-leadwire, 12-lead simultaneous acquisition with programmable lead configuration.

Processing

ECG Interpretation	Marquette [™] 12SL [™] ECG Analysis Program for Adults and Pediatrics
Computerized measurements	12-lead analysis
ECG analysis frequency	500 or 1000 samples/second/channel
Digital sampling rate	16000 samples/second/channel for normal data acquisition
Pace sampling rate	75K samples/second/channel
ECG on-screen preview	On-screen preview of acquired 10 second ECG waveform
Acquisition mode	Provides 10 seconds of instantaneous ECG acquisition
Dynamic range	AC Differential ± 5 mV, DC offset ± 300 mV
Resolution	4.88 μ V $\pm 1\%$ per LSB @ 500 SPS
Frequency range	0.04 to 150 Hz
Low cut off frequency	0.04 Hz (ADS off), 0.56 Hz (ADS On)
High cut off frequency	Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz
Common mode rejection	>135 dB (with 50/60 Hz filter ON)
Input impedance	>10M Ω @ 10 Hz
Patient leakage	<10 μ A (Normal Condition), <50 μ A (Single Fault Condition)
Lead detection	All disconnected lead detection except RL and RA

Heart rate meter	30 to 300 BPM
Operating system	Microsoft [®] Windows [®] Embedded Compact 7
Start-up time	Less than 30 seconds

Patient information

Supported patient information	Patient ID, secondary patient ID, visit ID, last name, first name, height, weight, gender, race, pacemaker patient, systolic BP, diastolic BP, location number, room, order number, phone number, medication, ordering physician, referring physician, attending physician, technician, test indication
-------------------------------	---

Display

Display type	7 in. color TFT display with support of minimum 32K colors
Display resolution	WVGA resolution – 800 x 480
Display data	Heart rate, patient ID, clock, battery power indicator, waveforms, lead lables, speed, gain and filter settings, warning messages, prompts, help messages, and 12-lead display

Writer

Writer technology	Thermal dot array
Writer speed`	5, 12.5, 25, and 50 mm/s
Number of traces	Up to 12 ECG traces
Writer sensitivity/gain	2.5, 5, 10, 20, 40 mm/mV
Writer speed accuracy	5, 12.5 mm/s @ $\pm 5\%$ and 25, 50 mm/s @ $\pm 2\%$
Writer amplitude accuracy	$\pm 5\%$

Writer resolution	Horizontal 40 dots/mm @ 25 mm/s, 8 dots/mm vertical
Paper type	Z-fold Thermal Paper with pre-printed grid and perforation with Queue mark or Queue hole
Paper size	8.46 in x 11 in (215 mm x 280 mm) Letter 8.27 in x 11.69 in (10 mm x 295 mm) A4 8.43 in x 11 in (214.2 mm x 279.4 mm) Modified Letter

Keyboard

Type	Membrane keyboard with tactile feedback – Soft function keys, alphanumeric keys (Qwerty key set), writer controls and Trim Pad cursor controls
------	--

Operating modes and additional features

Resting ECG mode	Records and prints 12-lead resting ECGs with 10 seconds duration as a standard feature
Arrhythmia mode	Continuously monitors ECG and prints report when arrhythmia events of the user-selected class occur
Exercise mode	Exercise mode for exercise stress testing
RR Analysis mode*	RR analysis for RR intervals analysis
Full Disclosure mode	Store upto 5 minutes of 1 lead data in PDF format
Hookup advisor	Provides visual indication of signal quality
Multi-language support	Supports 19 languages in User Interface and 31 languages in User Manual
Order manager	Provides an interface for managing orders
ADT and Order Query	Provides an interface for querying patient demographics and orders
File manager	Provides an interface for managing ECG Records
System setup	Provides an interface for managing Device Configuration

Stress/Pharma application options

Stress testing application	Ergometers supported include: eBike Treadmills supported include: T2100, T2000 Master's Step device without interface (acoustic signal only) <i>Note: Ergometer, Master Step, and Treadmill sold separately</i>
Pharma application options	- Date & Time Prompt upon log in - Auto Save and export to SD Card of Patient test record after acquisition - Audit trail export - CT Data Guard™ - High security login protection

External peripherals

Keyboard	Standard USB English Keyboard
Barcode reader	Jadak-1799
Barcode Symbolologies	Code 39, Code 39EX, Code 128, PDF-417, Interleaved Code 2 of 5, Data Matrix
Special Characters	In Italian, French, German, English and Spanish Languages

Communication

- Secured Digital card, Serial, LAN, and WIFI communicates outbound to MUSE™ and CardioSoft™
- LAN, and WIFI communicates inbound to MUSE
- MUSE Cardiology Information System and CardioSoft* compatible
- Bi-directional communication enabled with integration capabilities to MUSE, EMR, DICOM and DICOM modality work list systems workflow

RS232 serial cable Protocol	ECG Transmission with A5 and CSI
Supported MUSE/CardioSoft	Compatible with MUSE V 7.1.1, v8.0.1, v9.0.0 and NX CardioSoft/CS V6.51, V6.61, V6.71, V6.73 and V7
RJ45 Wired LAN	ECG Transmission with CSI, DCP Protocol, FTPS and Shared Directory‡
Wireless LAN (WIFI)	ECG Transmission with CSI, DCP Protocol, FTPS and Shared Directory‡

WiFi Authentication Protocols

Wireless Bridge Option:	Open, Shared, WPA2 with pre-shared key, WPA/WPA2 Mixed Mode with pre-shared key, WPA2 with PEAP, WPA/WPA2 Mixed Mode with PEAP, WPA2 with EAP-TLS, WPA/WPA2 Mixed Mode with EAP-TLS, WPA2 with EAP-TTLS, WPA/WPA2 Mixed Mode with EAP-TTLS, WPA2 with EAP-FAST, WPA/WPA2 Mixed Mode with EAP-FAST, WPA2 with LEAP, WPA/WPA2 Mixed Mode with LEAP
-------------------------	--

Embedded Wireless Module:	- Open - Shared - WPA – PSK* - WPA2-PSK* - WPA/WPA2 with PEAP - WPA/WPA2 with TLS - WPA/WPA2 with TTLS
---------------------------	--

Certain network settings are required for WIFI authentication. To determine whether your network is compatible, please refer to the MAC2000 site survey document DOC2368090.

*Not available in some countries.

‡Shared Directory require WINS

WiFi Encryption

Wireless Bridge Options:	Disabled (for Open authentication), WEP (for Shared and Open authentications) TKIP (for WPA/WPA2 Mixed Mode authentications), AES (for WPA & WPA2 authentications)
Embedded Wireless Module:	• Disabled (For Open authentication) • WEP (For Shared and Open authentications) • TKIP (for WPA-PSK1, WPA2-PSK1, WPA2 authentications) • AES (for WPA-PSK1, WPA2-PSK1, WPA2 & WPA22 authentications)

Storage

ECG Storage Format	XML format, Hilltop format, PDF storage format
Storage Capacity	Internal storage of 100 or 200 ECGs

Accessories

ECG Cables/Leadwires	IEC/AHA Value 10LD Patient Cable/Leadwire 10-lead IEC/AHA Patient trunk cable IEC/AHA Leadwire set (ECG 10-L w/resist, Banana) IEC/AHA Set of leadwires (4mm connector, 10 leads, defibrillator proof)
ECG Adapter	IEC/AHA Kit Adapter, 10 set Banana Electrode Prep Pads, CLIP Universal GE 10/Pkg
Electrodes	ECG Electrode Clamp (Large, 4/set) ECG Electrode Bulb (6/set) Baby MAC electrodes Silver Mactrode Plus 1000/CASE Electrode Application System KISS 10-lead
Other accessories	Country specific power cords Z-fold Thermal Paper with pre-printed grid and perforation with Queue mark or Queue hole of size: • 8.46 in x 11 in (215 mm x 280 mm) Letter • 8.27 in x 11.69 in (210 mm x 295 mm) A4 • 8.43 in x 11 in (214.2 mm x 279.4 mm) Modified Letter • 150 sheets/pack, 1500 sheets/case USB data matrix barcode scanner Secure Digital High Capacity Card – 2GB/4GB/8GB/16GB/32GB

Electrical

Power supply	Internal AC/DC or battery operation
AC/DC operation specifications	
Input voltage:	100 to 240 VAC $\pm 10\%$
Input current:	Maximum 1.5A in voltage range 115 V to 230 V AC
Input frequency:	47 to 63 Hz
Battery specifications	
Battery type:	Replaceable and rechargeable, Lithium Ion
Battery capacity:	14.54V nominal voltage @ 3.5 AH – 10% 150 single page resting ECG recordings or 6 Hours (typical) of continuous monitoring without printing, at a minimum.
Battery charge time:	Approximately 3.5 hours after low battery shut down (with device off) to 90% full capacity

Physical specification

Height	7.87 inches (200 mm)
Width	15.35 inches (390 mm)
Depth	Depth 12.99 inches (330 mm)
Weight	Approx. 11.02 lbs (5 kg) including battery, without paper

Environmental specification

Temperature	Operating: 50°F to 104°F (10°C to 40°C) Transport/storage: -104°F to 158°F (-40°C to 70°C)
Humidity	Operating: 20% to 95% RH non-condensing Transport/storage: 15% to 95% RH non-condensing
Pressure	Operating: 700 to 1060 hPA (Altitude range: 3010.9 to -381.9 meters) Transport/storage: 500 to 1060 hPA (Altitude range: 5570 to -380 meters)

Safety and regulatory

- CE marking for Council Directive 93/42/EEC concerning medical devices
- EN 60601-1 (IEC 60601-1) Medical electrical equipment – Part 1: General Requirements for Safety
- IEC 60601-1-2 General Requirements for Safety Electromagnetic Compatibility
- IEC 60601-2-25 Safety of Electrocardiographs
- UL 60601-1: 2006 UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety
- CAN/CSA C22.2 No. 601.1 M90
- IEC 60601-1-6 General Requirements for Safety – Usability

¹ WPA-PSK and WPA2-PSK are personal authentication frameworks.

² WPA and WPA2 are enterprise authentication frameworks.

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
U.S.A.

www.gehealthcare.com

©2020 General Electric Company – All rights reserved.

General Electric Company reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. GE, GE Monogram, imagination at work, 12SL, CardioSoft, CT Data Guard, MAC, Marquette, and MUSE are trademarks of General Electric Company. Microsoft and Windows are registered trademarks of Microsoft Corporation in the United States and/or other countries. GE Healthcare, a division of General Electric Company.

MAC 2000 V1.1 SP7 onwards

DOC1303761 Rev 9



September 2022

AC 2000 ECG Analysis System

Simple is better



Simple is Smart

Introducing the MAC™ 2000 ECG
Analysis System
support you want in a
connected system that's intuitive
easy to use.
ly, really smart.

0 | Simple is better



Simple is Smart

Introducing the MAC™ 2000 ECG Analysis System

support you want in a connected
system that's intuitive and easy to use.
Simply, really smart.



Simple is Smart

Simple



Connected



Advanced Technology



0 | Simple is better



Simple

Simple is Productive



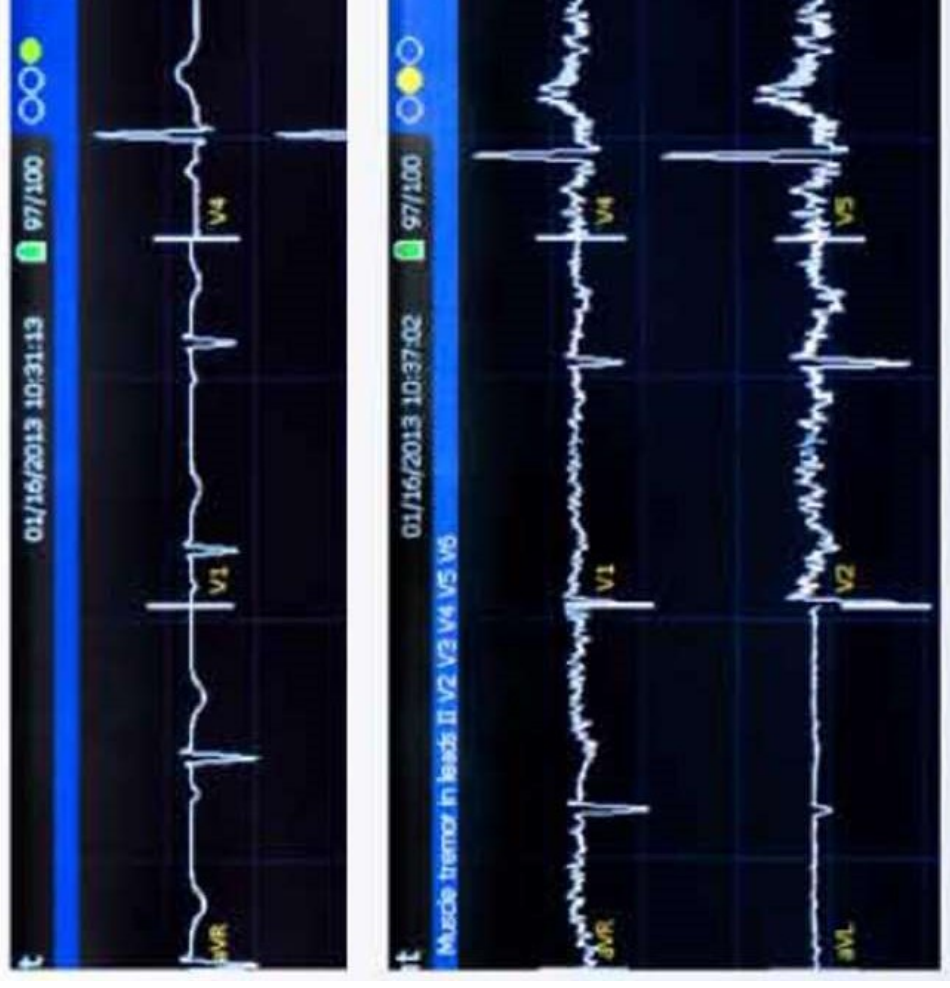
Tools to simplify your ECG workflow

- Hookup Advisor™ program helps clinicians identify a quality signal prior to acquisition
- On-screen 12 lead results help streamline ECG review and analysis
- Convenient computer-based training tools to bring your team up to speed quickly
- Available in exercise testing configuration

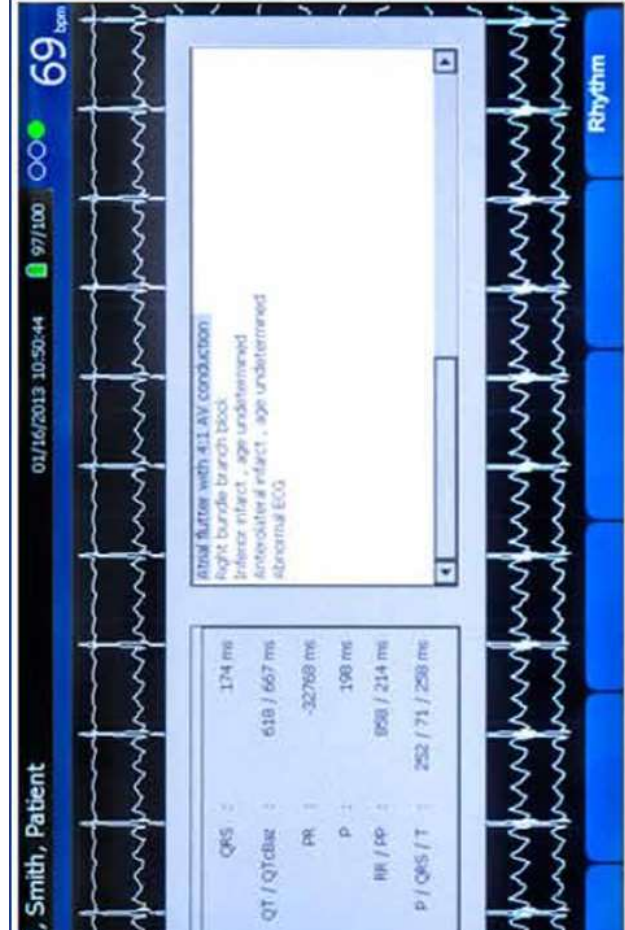
Simple is Productive

Hookup Advisor program

- Hookup Advisor program helps clinicians identify a quality signal prior to acquisition
- identifies the type of noise & leads affected
- Helps clinicians avoid costly repeat ECGs



Simple is Productive



On-screen 12-lead results

- Help to streamline ECG review and analysis
- 12-lead waveforms, measurements, computerized Marquette™ 12SL™ interpretation available as soon as ECG is recorded

Simple is Productive

Computer-based training

Provides a thorough look at the features and functionality of the MAC 2000 system

Modular design of the training

encourages user interaction

Move through basic system

overview, acquiring an ECG,

acquiring an arrhythmia report,

completing a stress ECG test, and

managing patient data

Facilitates on-demand initial and

refresher training



Simple is Productive



Simple is better

Stress testing configuration

- Expanded capability to help you make the most of your device investment
- Available for use with GE brand ergometers and treadmills



Connected

ple is connected

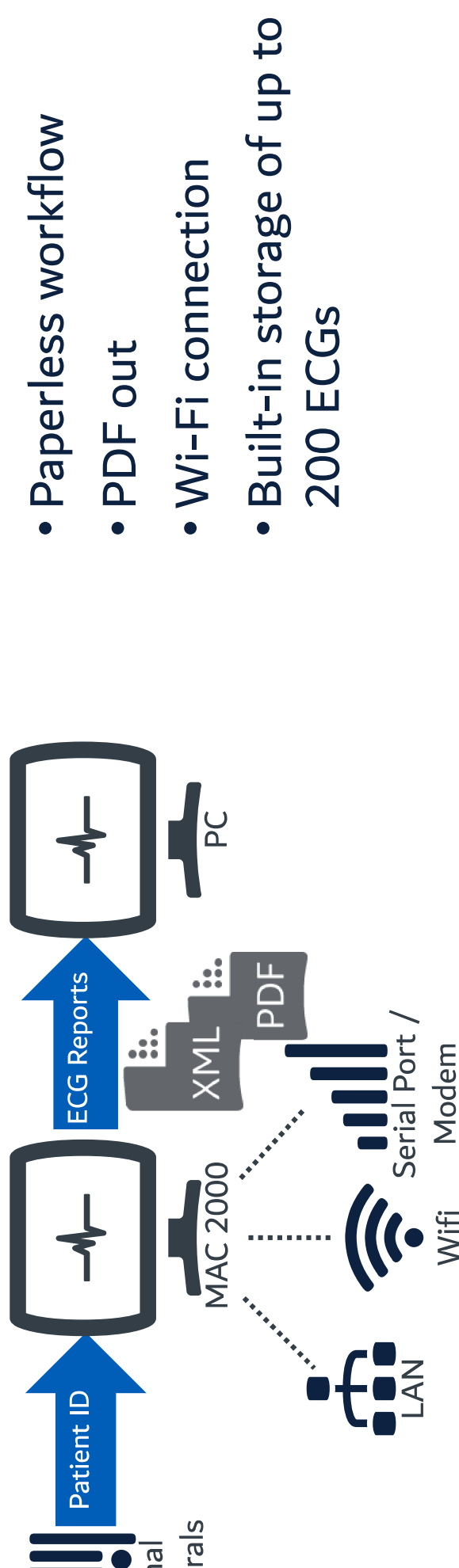


0 | Simple is better

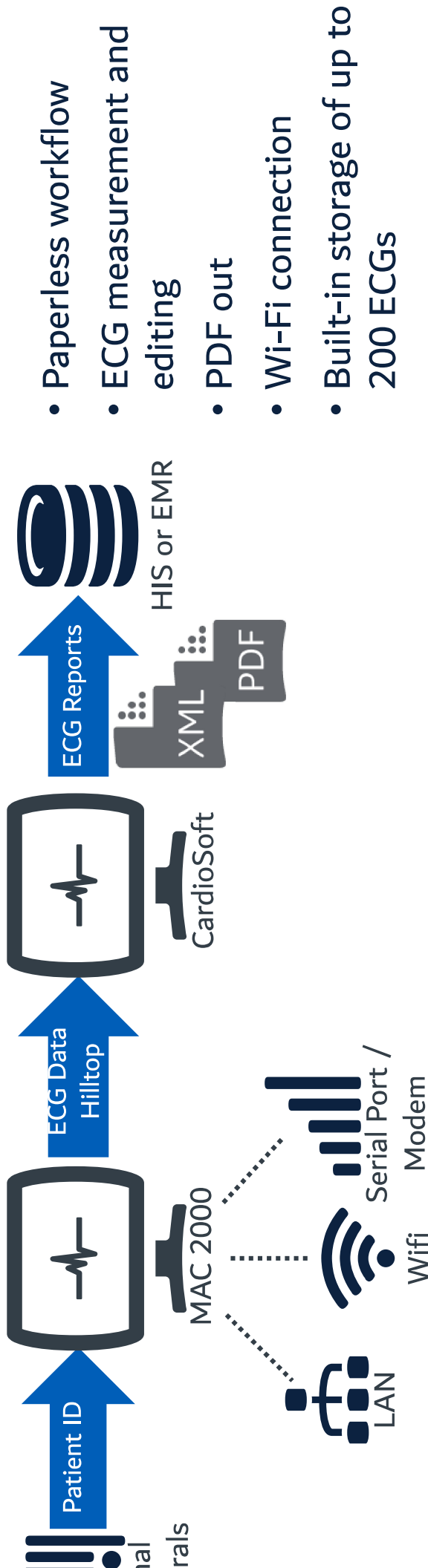
Your link to ECG data connectivity

- Seamless connectivity with the MUS cardiology system and the CardioSoft program
- Transfer data via Wi-Fi, LAN, SD card, modem, and serial ports
- PDF and XML export capabilities

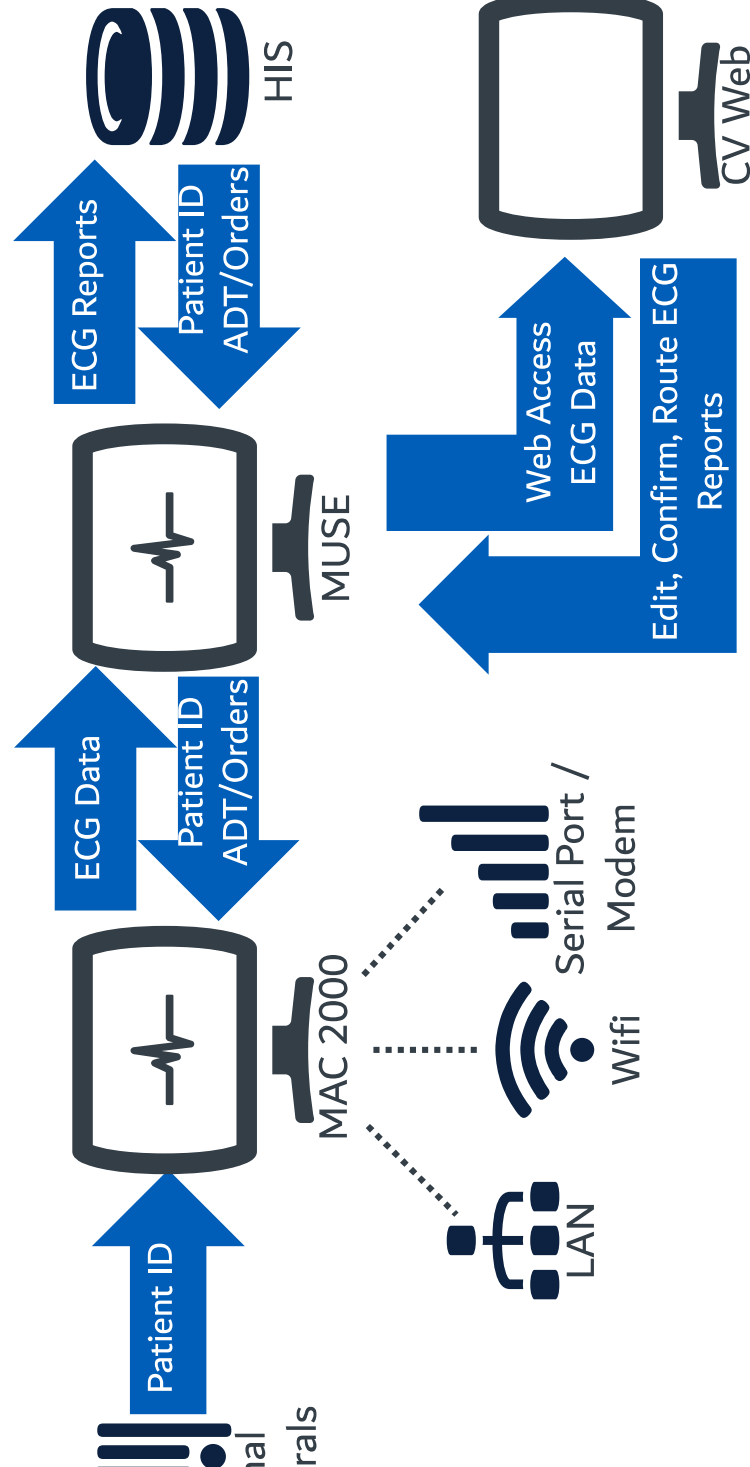
C 2000 workflow with shared directory/PC workstation



C 2000 workflow with CardioSoft Diagnostic Program



MAC 2000 workflow with MUSE Cardiology Information System



- Bi-directional communication with HIS system
- Orders and ADT query capabilities
- Web-enabled ECG report editing possible with CV Web
- Fast communication with D protocol
- Optional barcode reader functionality



Secure

Simple is Secure



Patient data encryption



Automatic, time configurable
log-off



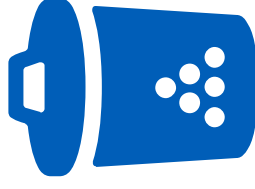
Username and password
authentication



Site and location support



Audit trail, activity log



Automatic patient data
deletion after transmission

At a few ways this approach is manifested in MAC 2000



We encrypt all patient information stored on the MAC 2000 using 128 bit encryption software.



As an added layer of security, the MAC 2000 offers the option to create usernames and passwords.



To keep the system safe MAC 2000 can only receive inbound traffic from GE's MUSE, Gateways and FTP servers with a designated port.



The MAC 2000 can monitor and record security-related activities, such as logins and network connections, for audit.



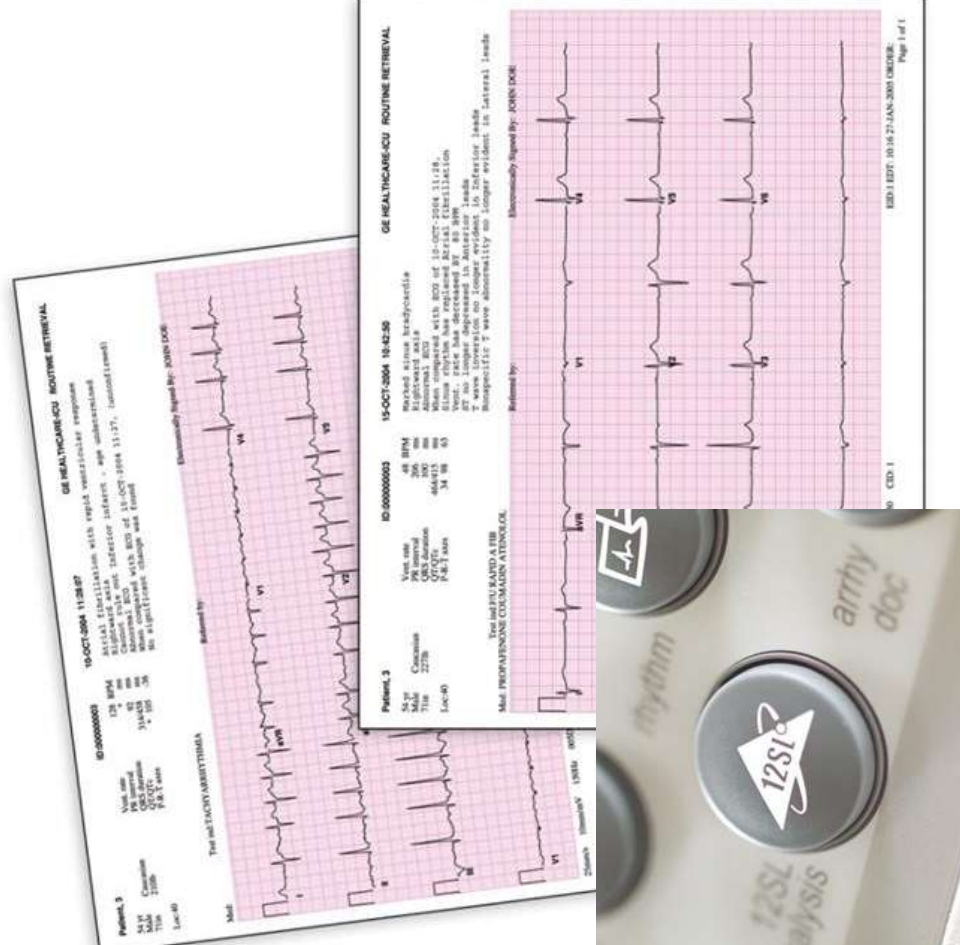
Advanced Technology

quette™ 12SL™

- Over 30 years of innovation and development
- Over 150 scientific references¹
- Validated against clinically-correlated databases for accuracy¹
- ACI-TIPI option calculates probability of the presence of Acute Cardiac Ischemia
- Gender-specific interpretation has been shown to provide a 25% relative improvement in detection of Acute Inferior MI in women under 60 years age²

¹for more details please refer to the GE 12SL statement of validation and accuracy

²Xue, J. et al. "A New Method to Incorporate Age and Gender into the Criteria for Detection of Acute Inferior Myocardial Infarction." *J Electrocardiol.* 34(4) (Part 2):229-234



C 2000 Solution for Pharma Clinical Trials



- Hookup Advisor helps the clinician to identify a quality signal prior to acquisition. Less noise means reduced QT measurement variability³
- CT Data Guard helps in capturing clinical details, and records the same in ECG report
- CFR Audit Trail supports 21 CFR Part 312 compliance requirements

³ Farrell, R.M and Rowlandson, G.I., "The Effects of Noise on Computerized Electrocardiogram measurements." J Electrocardiol, 2006, 39(4 Suppl): p.S165-7

Suction Electrode Application System

provide consistent connection to
patients
Fast and easy electrode applications in
the cardiology department
operates with a slight suction regulated
the electronically controlled suction
pump via high sensitive sensors



C 2000 ECG Analysis System

ple is here





Building a world that works

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. **CE 651490**
Issued To: **Micropace Pty Ltd**
41/159 Arthur Street
Homebush West
New South Wales
2140
Australia

In respect of:

Design and manufacture of Cardiac Stimulators for diagnostic electrical stimulation of the heart for initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-04-27**

Date: **2020-03-04**

Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 1 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Supplementary Information to CE 651490

Issued To:

Micropace Pty Ltd
41/159 Arthur Street
Homebush West
New South Wales
2140
Australia

Class IIb		
GMDN	Device or Generic Device Group	Intended purpose as per IFU
35976	Stimulator, electrical, cardiac, diagnostic	The Micropace Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of initiation and termination of tachyarrhythmias, refractory measurements and measurements of electrical conduction.

First Issued: **2016-04-27**Date: **2020-03-04**Expiry Date: **2024-05-26**

...making excellence a habit.™

Page 2 of 2

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No: **CE 651490**
Date: **2020-03-04**
Issued To: **Micropace Pty Ltd**
41/159 Arthur Street
Homebush West
New South Wales
2140
Australia

Subcontractor:**Service(s) supplied**

Advena Ltd
Tower Business Center
2nd Floor, Tower Street
Swatar
BKR 4013
Malta

EU Representative

Micropace EP Inc.,
3205 West Warner Avenue
Santa Ana
California
92704
USA

Manufacture

...making excellence a habit.™

EC Certificate - Full Quality Assurance System

Certificate History

Certificate No: **CE 651490**
Date: **2020-03-04**
Issued To: **Micropace Pty Ltd**
41/159 Arthur Street
Homebush West
New South Wales
2140
Australia

Date	Reference Number	Action
27 April 2016	8501818	Initial Issue. Transferred from another Notified Body.
09 June 2017	8676990	Change of manufacturer address from "Unit 7, 186-188 Canterbury Road, Canterbury, New South Wales, 2193, Australia" to 41/159 Arthur Street, Homebush West, New South Wales, 2140, Australia"
12 February 2019	8764551	Traceable to NB 0086.
28 March 2019	9717553	Certificate re-issue to change EU representative address from United Kingdom to Malta.
Current	9733043	Certificate renewal. Addition of product table.

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'Assurance Qualité / Approval of full Quality Assurance System

ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux

ANNEX II excluding section 4 DIRECTIVE 93/42/EEC concerning medical devices

Pour les dispositifs de classe III, un certificat CE de conception est requis

For class III devices, a EC design certificate is required

Fabricant / Manufacturer

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

Catégorie du(des) dispositif(s) / Device(s) category

Equipements de cardiologie et systèmes de surveillance de patients
Systèmes de surveillance clinique et systèmes de télémétrie médicale
Baie de cathétérisme et/ou d'électrophysiologie
Moniteurs cardiaques et leurs accessoires
Moniteurs de surveillance patient
Systèmes d'électrocardiographie et de surveillance de patients

Cardiology equipment and patient monitoring systems
Clinical Monitoring Systems and Medical Telemetry Systems
Catheterization and/or Electrophysiology lab System
Cardiology monitors and accessories
Patient monitors
Electrocardiographs and patient monitoring systems

Voir document complémentaire GMED / See GMED additional document
n° 38313

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P602818, P601202, le système d'assurance qualité – pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P602818, P601202, the quality system - for design, manufacturing and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue.
The validity of the certificate is subject to periodic or unexpected verification.

Début de validité / Effective date : June 8th, 2021 (included)

Valable jusqu'au / Expiry date : May 26th, 2024 (included)

DocuSigned by:

A1D80E08C60D47A...

Lionel DREUX
Certification Director

GMED – 7550 rev. 22
Renouvelle le certificat 7550-21

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

Ce document complémentaire GMED n° 38313 rev. 1 atteste de la validité du certificat CE N° 7550 rev. 22 au regard des informations listées ci-dessous.

This GMED additional document n° 38313 rev. 1 attests to the validity of EC certificate N° 7550 rev. 22 with regard to the information listed below.

Fabricant / Manufacturer:

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

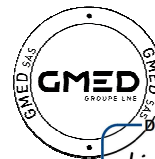
Identification des dispositifs / Identification of devices

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM <i>MD class</i>
Patient monitor, Central unit	Central Station (CSCS)	IIb
Patient monitor module, multiparameter	Patient Data Module (PDM)	IIb
Patient monitor, multiparameter	B20	IIb
Patient monitor, multiparameter	B40	IIb
Patient Monitor, multiparameter	B105	IIb
Patient Monitor, multiparameter	B125	IIb
Patient Monitor, multiparameter	CARESCAPE ONE	IIb
Transportable physiologic monitoring system	V100	IIb
Telemetry system, electrocardiograph	ApexPro Telemetry System	IIb
Clinical monitoring systems	Unity Network ID	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	MacLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	CardioLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	ComboLab	IIb

GMED **0459**

GMED - 38313 rev. 1

Renouvelle le document n° 38313 rev. 0



DocuSigned by:

Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

Désignation du dispositif / Accessoires marqués CE <i>Device designation / CE marked accessories</i>	Réf commerciale du dispositif ou code article <i>Device commercial reference or article code</i>	Classe du DM MD class
Electrocardiograph, Holter analyzer	Mars	Ila
Electrocardiograph, Holter analyzer	Mars SP4	Ila
Information system software, application program, cardiology	MUSE – SW Only	Ila
Information system software, application program, cardiology	CV Web	Ila
ECG Acquisition module	CAM 14V2	Ila
ECG Acquisition module	CAM HD	Ila
Interpretive multichannel electrocardiograph	MAC 2000	Ila
Interpretive multichannel electrocardiograph	MAC 600	Ila
Interpretive multichannel electrocardiograph	MAC VU360	Ila
Stress exercise monitoring system, cardiac	Case	Ila
Stress exercise monitoring system, cardiac	Cardiosoft / CS	Ila
Stress exercise monitoring system, cardiac	Cardiosoft / CS WIN8	Ila
Electrocardiograph, Electrodes	KISS	Ila

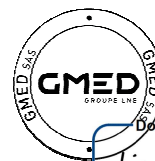
Site couvert et Activités / Location and Activities

Site / Location	Activités / Activities
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC 8200 WEST TOWER AVENUE MILWAUKEE, WISCONSIN 53223 - USA	Siège social – responsable de la mise sur le marché Conception, fabrication et contrôle final <i>Headquarters – legal manufacturer Design, manufacture and final control</i>

GMED	0459
-------------	-------------

GMED - 38313 rev. 1

Renouvelle le document n° 38313 rev. 0



DocuSigned by:

Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director



Versa trolley

Biostimulation laser therapy
 Electrotherapy
 High power laser therapy
 Magnetotherapy
 Shockwave therapy
 Ultrasound therapy



Features

product code	A-AM-AST-VSA
compatibility with ASTAR units / accessories	✓
running system with brakes	✓
shelves height adjustment (second, third and for CPEP applicators)	✓

General technical parameters

upper shelf load capacity	max 10 kg
total load capacity of the bottom shelf (with drawer and contents)	max 7 kg
bottom shelf adjustment range	approx. 60 cm
external dimension of the upper shelf (WxD)	58,0 x 34,0 cm
internal dimension of the upper shelf (WxD)	39,5 x 30,0 cm
external dimension of the bottom shelf (WxD)	40,0 x 26,0 cm
external dimension of the drawer (WxDxH)	39,0 x 33,0 x 9,0 cm
internal size of the drawer (WxDxH)	28,5 x 18,5 x 8,0 cm
trolley size (WxDxH)	58,0 x 49,0 x 87,5 cm
weight	13,9 kg

Dedicated for

Sonaris M	✓
Sonaris S	✓
Polaris 2	✓
Etius U	✓
Etius LM	✓
Etius ULM	✓
Polaris HP S	✓
Polaris HP M	✓
PHG 100A	✓
PHG 200A	✓

PHG 300A	✓
PHG 400C	✓
PHG 500I	✓
PHG 601C	✓
PHG 701C	✓
PHG 701I	✓
PhysioGo.Lite LASER	✓